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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/625,628	07/24/2003	Gerrit Koppert	KOPPERT1A	9050
1444	7590	08/11/2005	EXAMINER	
BROWDY AND NEIMARK, P.L.L.C. 624 NINTH STREET, NW SUITE 300 WASHINGTON, DC 20001-5303				ROBINSON, KEITH O NEAL
ART UNIT		PAPER NUMBER		
		1638		

DATE MAILED: 08/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/625,628	KOPPERT, GERRIT
	Examiner Keith O. Robinson, Ph.D.	Art Unit 1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 08 June 2005.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-17 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 24 July 2003 is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____.
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>July 24, 2003</u> .	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
	6) <input type="checkbox"/> Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's arguments, see 'Reply to Election Requirement', filed 8 June 2005, with respect to the species election requirement have been fully considered and are persuasive. The election of species requirement has been withdrawn.

Claim Objections

2. Claims 3-6, 8, 9, 11, 12, 13 and 14-15 objected to because of the following informalities:

(a) In claims 3-6, 8, 9, 11, and 14-15 the first word "A" should be replaced with – The--.

(b) In claim 12, "Material from a plant" should be replaced with –Material from the plant--.

(c) Claim 13 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer other claims in the alternative only.

See MPEP § 608.01(n).

Appropriate correction is required.

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11

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F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1-2 and 5-16 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-14 of U.S. Patent No. 6,686,517. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant application uses the same method steps and uses the same materials, namely *Raphanus* plants, including ATCC No. PTA-3630.

Claim Rejections - 35 USC § 112, first paragraph – Written Description

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to

one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1-6, 8, 9, and 12-17 are broadly drawn to any plant of the genus *Raphanus* or of the species *Raphanus sativa* having anthocyanins at a level of at least 100 nmol per gram fresh weight of sprout when grown at a temperature of 10-35 degrees Celsius under high humidity and a daily cycle of light and methods of using said plants.

The specification fails to provide a written description of the broad genus of *Raphanus* and *Raphanus sativa* plants having anthocyanins at a level of at least 100 nmol per gram fresh weight of sprout when grown at a temperature of 10-35 degrees Celsius under high humidity and a daily cycle of light with regard to their genetic, morphological, and/or physiological characteristics.

The specification only provides a written description for *Raphanus* line V33 having large quantities of anthocyanins (see page 15, lines 15-25 and page 16, Table 1).

Claims 7, 10 and 11 are broadly drawn to a container of *Raphanus* sprouts or plantlets.

The specification fails to provide a written description of the broad genus of *Raphanus* sprouts or plantlets having anthocyanins at a level of at least 100 nmol per gram fresh weight of sprout when grown at a temperature of 10-35 degrees Celsius under high humidity and a daily cycle of light with regard to their genetic, morphological, and/or physiological characteristics.

The specification only provides a written description for *Raphanus* lines V33 having large quantities of anthocyanins (see page 15, lines 15-25 and page 16, Table 1).

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that a written description of an invention "requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials". University of California v. Eli Lilly and Co., 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The court also concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not description of that material". Id. Further, the court held that to adequately describe a claimed genus, Patent Owner must describe a representative number of the species of the claimed genus, and that one of skill in the art should be able to "visualize or recognize the identity of the members of the genus". Id.

See MPEP Section 2163, page 156 of Chapter 2100 of the August 2001 version, column 2, bottom paragraph, where it is taught that

[T]he claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.

Given the failure of the specification to describe the claimed plant, methods of using it are also inadequately described. Accordingly, one skilled in the art would not have recognized Applicants to have been in possession of the claimed invention. See the written description guidelines published in Federal Register/ Vol. 66, No. 4/ Friday January 4, 2001/ Notices: pp. 1099-1111.

Claim Rejections - 35 USC § 112, first paragraph - Enablement

7. Claims 1-17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 4 and 17 are broadly drawn to any *Raphanus* plant, sprouts and plantlets thereof, and methods of using said plant produced using *Raphanus* lines CGN 6924, CGN 7240, ATCC No. PTA-3630, or combinations thereof. Since the plant is essential to the claimed inventions, it must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the plant is not so obtainable or available, the requirements of 35 U.S.C. 112 may be satisfied by a deposit of the plant. The specification does not disclose a repeatable process to obtain the plant and it is not apparent if the plant is readily available to the public. Thus, a deposit is required for enablement purposes. A deposit of 2500 seed of each of the claimed

embodiments is considered sufficient to ensure public availability. If the deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the specific strain has been deposited under the Budapest Treaty and that the strain will be irrevocably and without restriction or condition released to the public upon the issuance of a patent, would satisfy the deposit requirement herein.

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 C.F.R. 1.801-1.809, applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that

- (a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;
- (b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;
- (c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer;
- (d) a test of the viability of the biological material at the time of deposit (see 37 C.F.R. 1.807) and,
- (e) the deposit will be replaced if it should ever become inviable.

In re Wands, 858F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988) lists eight considerations for determining whether or not undue experimentation would be necessary to practice an invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claims.

Claims 1-6, 8, 9, and 12-17 are broadly drawn to any plant of the genus *Raphanus* or of the species *Raphanus sativa* having anthocyanins at a level of at least 100 nmol per gram fresh weight of sprout and methods of using said plants.

The specification fails to provide any guidance regarding the broad genus of *Raphanus* and *Raphanus sativa* plants with regard to their genetic, morphological, and/or physiological characteristics. The specification also fails to provide any working examples or evidence of the broad genus of *Raphanus* and *Raphanus sativa* plants having anthocyanins at a level of at least 100 nmol per gram fresh weight of sprout.

The specification only provides guidance for *Raphanus sativa* line V33 and only shows evidence of *Raphanus sativa* line V33 having anthocyanin levels of at least 100 nmol (see page 16, Tables 1 and 2).

Claims 7, 10 and 11 are broadly drawn to a container of *Raphanus* sprouts or plantlets.

The specification fails to provide any guidance regarding the broad genus of *Raphanus* sprouts or plantlets having anthocyanins at a level of at least 100 nmol per

gram fresh weight of sprout with regard to their genetic, morphological, and/or physiological characteristics. The specification also fails to provide any working examples of evidence for the broad genus of *Raphanus* sprouts or plantlets.

The specification only provides guidance for *Raphanus sativa* line V33 and only shows evidence of *Raphanus sativa* line V33 having anthocyanin levels of at least 100 nmol (see page 16, Tables 1 and 2).

Hoshi et al (Bot. Mag. Tokyo 88: 249-254, 1975) teach that the trait of anthocyanin accumulation in *Raphanus sativa* is conferred by expression of multiple genes from multiple loci, whose expression is incompletely penetrant for conferring a trait of anthocyanin accumulation and that a variety of modifier genes are epistatic to at least two dominant alleles which confer a trait of anthocyanin accumulation in radish (see pages 252-253, Tables 4-7; and page 253, lines 1-3).

Savoskin et al (Sov. Genet. 7(11): 1393-1396, 1974) teach that in tetraploid *Raphanus* species, the genetic interactions that confer a trait of anthocyanin accumulation are even more polygenic and unpredictably genetically complex (see page 1395, Tables 1 and 2 and lines 1-38).

Given the breadth of the claims, the lack of guidance regarding the broad genus of *Raphanus* and *Raphanus sativa* plants with regard to their genetic, morphological, and/or physiological characteristics, the lack of working examples with regard to the broad genus of *Raphanus* and *Raphanus sativa* plants having anthocyanins at a level of at least 100 nmol per gram fresh weight of sprout, and the unpredictability gene

expression and genetic interactions regarding anthocyanin accumulation, it would require undue trial and error experimentation to make and use the invention as claimed.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-12, and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Giusti et al (J. Food Sci. 61(2): 322-326, 1996).

The claims read on any plant of the genus *Raphanus* or *Raphanus sativa* grown under a medium comprising water, at temperatures between 10-35 degrees Celsius under a daily light cycle wherein said plant comprises anthocyanin levels of at least 100 nmol per gram fresh weight of sprout and wherein said anthocyanins have an anthocyanidin moiety of that of formula 1.

Giusti et al disclose the *Raphanus sativa* cultivar 'Fuego' which has anthocyanin levels of at least 100 nmol/g with an absorbance maximum in the range of 515-550 nm comprising an anthocyanin moiety that has the structure of formula 1 (see pages 324-325, Figures 1-6; and page 323, Table 1). It is inherent that the sprout would have a height of less than 20 cm, at any particular time after seed germination, under some environmental growth condition set of parameters. See *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985), which teaches that a product-by-process claim may be properly

rejectable over prior art teaching the same product produced by a different process, if the process of making the product fails to distinguish the two products. See *In re Best*, 195 USPQ 430, 433 (CCPA 1997), which teaches that where the prior art product seems to be identical to the claimed product, except that the prior art is silent as to a particularly claimed characteristic or property, then the burden shifts to Applicant to provide evidence that the prior art would neither anticipate nor render obvious the claimed invention.

10. Claim 16 is rejected under 35 U.S.C. 102(b) as being anticipated by Giusti et al (J. Agric. Food Chem. 46: 4858-4863, 1998).

The claim reads on a method for producing anthocyanin comprising growing any *Raphanus* plant, harvesting said plant, recovering anthocyanin from said plant, and optionally, purifying said anthocyanin.

Giusti et al (1998) disclose a method for producing anthocyanin comprising growing a *Raphanus* plant, harvesting said plant, recovering anthocyanin from said plant and purifying said anthocyanin (see page 4859, first column, line 1 to second column, end of sixth paragraph).

Claim Rejections - 35 USC § 102/103

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. Claims 1-12 and 17 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Giusti et al (J. Food Sci. 63(2): 219-224, 1998).

The claims read on any plant of the genus *Raphanus* or *Raphanus sativa* grown under a medium comprising water, at temperatures between 10-35 degrees Celsius under a daily light cycle wherein said plant comprises anthocyanin levels of at least 100 nmol per gram fresh weight of sprout and wherein said anthocyanins have an anthocyanidin moiety of that of formula 1.

Giusti et al (1998b) disclose 'Fuego', 'Saxa Korto' and 'Arista' *Raphanus sativa* cultivars with the characteristic of a level of at least 100 nmol/g fresh weight anthocyanin (see pages 221-223, Tables 1-6 and Figure 1).

Claims 4 and 17 are broadly drawn to any radish plant that has the limitation that the *Raphanus* plant comprises any plant produced by an unspecified number and combination of crosses with any number of nonspecified parentals, but whose pedigree comprises at least one of CGN 6924, CGN 7240 or ATCC No. PTA-3630 plants as an ancestor.

The 'Fuego', 'Saxa Korto' and 'Arista' *Raphanus sativa* cultivars taught by Giusti et al differs from the claimed plants only in their derivation from having a pedigree that includes CGN 6924, CGN 7240 or ATCC No. PTA-3630 plants as an ancestor. However, the use of CGN 6924, CGN 7240 or ATCC No. PTA-3630 plants as an ancestor in an unspecified number of crosses and with unspecified breeding partners would not confer a unique characteristic to the claimed plants which would distinguish them from the prior art plants, in view of the loss of CGN 6924, CGN 7240 or ATCC No. PTA-3630-derived genetic material with each cross to an unrelated partner. See *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985), which teaches that a product-by-process claim may be properly rejectable over prior art teaching the same product produced by a different process, if the process of making the product fails to distinguish the two products.

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

15. Claims 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Giusti et al (1996) in view of Khare et al (Indian J. Plant Physiol. 34: 235-241, 1991), and further in view of Poindexter et al (U.S. Patent 3,643,376).

The claims read on a method for producing any radish sprout in a container or apparatus that provides control over humidity, light, and temperature growth conditions and the chilling of seedlings at 1-6 degrees Celsius.

Giusti et al teach the radish plants as outlined in the 35 U.S.C. 102(b) rejection above.

Giusti et al do not teach the use of a container or rotating drum apparatus for growing plants, or growing plantlets under a particular temperature, light, or humidity environmental condition.

Khare et al teach the growing of germinating radish seeds for 24 hours at 25 degrees Celsius in closed containers containing a suitable germination medium comprising water and filter paper, with a humidity greater than 70%, transferring germinated radish seeds and growing plantlets at 25 degrees Celsius in liquid medium in containers for 72 hours (see page 236, lines 18-37).

Poindexter et al teach the growing of sprouts, plantlets, or seedlings in a rotating metal drum apparatus (see column 1, lines 35-39 and Figures 1-2).

Poindexter et al suggest that any commercially valuable seedling, plantlet, or sprout, which include radish seedlings, would benefit under the controlled environmental conditions that could be uniformly established in their rotating drum apparatus, because secondary metabolite production in these plant materials would be more stable (see column 1, lines 35-54).

It would have been obvious to one of skill in the art to combine the radish plant materials taught by Giusti et al; the controlled environmental growth conditions and

method steps taught by Khare et al; and the rotating drum apparatus an its ability to program uniform growth conditions, as taught by Poindexter et al; as suggested by Khare et al and Poindexter et al, to make the broadly claimed invention. Adding a final method step of chilling the seedlings at 1-6 degrees Celsius would have been an obvious design choice for one of ordinary skill in the art.

Conclusion

16. No claims are allowed.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Keith O. Robinson, Ph.D. whose telephone number is 571-272-2918. The examiner can normally be reached on Monday - Friday 7:30 am - 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on 571-272-0745. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

20. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Keith O. Robinson, Ph.D.

August 1, 2005

DAVID H. KRUSE, PH.D.
PRIMARY EXAMINER

